Agilent Technologies

Declaration of System Validation

We herewith inform you that the software product/system

Product Numbers	**G2946CA and G2949CA**
Product Name	**Agilent Technologies 2100 Bioanalyzer expert software**
Revision Number	**B.02.0x**

was developed according to the quality process and software life cycle followed by the Life Science and Chemical Analysis divisions of Agilent Technologies. Life cycle check-point details were reviewed and approved by management. The product was found to meet its functional and performance specifications, and release criteria at release to shipment.
In order to fulfill the validation requirements of the users of this product according to current regulations and quality standards including, but not limited to, 21 CFR 210 (Good Manufacturing Practice for Drugs), 21 CFR 211 (current Good Manufacturing Practice for finished pharmaceuticals), 21 CFR 58 (Good Laboratory Practice), 21 CFR Part 11 (Electronic Records and Signatures) Agilent Technologies will make the source code and the documents referenced on page 2 of this declaration available to an authorized governmental or regulatory agency for inspection at its Pharmaceutical Solutions Unit, Waldbronn, Germany (terms and conditions to be negotiated).
Agilent Technologies will maintain possession of all documents and their reproductions and may require a confidential disclosure agreement to be provided by those requiring access to these documents.

Date: **June 2005**

Engineering manager: Herbert Wiederoder

(PHS)

Quality manager: G. Gröbe

(PHS)

☑ **Product description**

Specifications

☑ **Lifecycle Phase Transition Approvals**

Proposal
Investigation
Design
Implementation
Test
Manufacturing Release

☑ **Software Quality Assurance**

Quality Plan
Release criteria
Software Test Plan
Test procedures and acceptance criteria
Definition of expected test results
Test cases, test suites, test results
System change request tracking and reporting

☑ **Documentation and Change Management**

Requirements Management
Software Configuration Management
Change Management Process
Coding Standards

☑ **Source Code**

G2946-90502

Part Number: **G2946-90502**

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